vice or component which does not meet its performance specifications shall be investigated. A written record of the investigation, including conclusions and followup, shall be made. A critical device shall not leave the control of the manufacturer for distribution until all acceptance records and test results have been checked by a designated individual(s). Such individual(s) shall assure that all records and documentation required for the device history record are present and complete, and show that release of the device was consistent with the release criteria. Such individual(s) shall authorize, by signature, the release of the device for distribution.

§ 820.162 Failure investigation.

After a device has been released for distribution, any failure of that device or any of its components to meet performance specifications shall be investigated. A written record of the investigation, including conclusions and followup, shall be made.

Subpart J—Records

§ 820.180 General requirements.

All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of the Food and Drug Administration designated to perform inspections. Such records shall be available for review and copying by such employees. Except as specifically provided elsewhere, the following general provisions shall apply to all records required by this part.

(a) *Confidentiality.* Those records deemed confidential by the manufacturer may be marked to aid the Food and Drug Administration in determining whether information may be disclosed under the public information regulation in Part 20 of this chapter.

(b) *Record retention period.* All required records pertaining to a device shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer. Photostatic or other reproductions of records required by this part may be used.

§ 820.181 Device master record.

The device master record shall be prepared, dated, and signed by a designated individual(s). Any changes in the device master record shall be authorized in writing by the signature of a designated individual(s). Any approval forms shall be part of the device master record. The device master record for each type of device shall include, or refer to the location of, the following information:

(a) Device specifications including appropriate drawings, composition, formulation, and component specifications.

(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications.

(c) Quality assurance procedures and specifications including quality assurance checks used and the quality assurance apparatus used.

(d) Packaging and labeling specifications including methods and processes used.

§ 820.182 Critical devices, device master record.

In addition to the requirements of § 820.181, the device master record for a critical device shall include or refer to the location of the following information:

(a) *Critical components and critical component suppliers.* Full information concerning critical components and critical component suppliers, including the complete specifications of all critical components, the sources where they may be obtained, and written copies of any agreements made with suppliers under § 820.81(b).

(b) *Labels and labeling.* Complete labeling procedures for the individual device and copies of all approved labels and other labeling.

§ 820.184 Device history record.

A device history record shall be maintained to demonstrate that the device is manufactured in accordance with the device master record. The device history record shall include, or